REMARKS

In the Office Action, claims 33-36 are rejected under 35 U.S.C. §102 or §103 as allegedly unpatentable over U.S. Patent No. 4,443,441 (Galin). Applicant believes that the rejections should be withdrawn at least in view of the reasons set forth below.

Of claims 33-36, claim 33 is the sole independent claim which recites an ophthalmic formulation in aqueous solution for topical administration including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. The claimed ophthalmic formulation with active phentolamine compound can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Indeed, Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision by reducing pupil size in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Specification, Examples 1 and 2; Tables 1 and 2; and corresponding text. Claim 33 has been amended to recite further that the phentolamine-based formulation is in a therapeutic amount and in a single dose per day of use to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. See, Specification, page 19 at lines 8-9.

In direct contrast, Galin indicates that "[t]he approximately one drop dose can be repeated several times per day…". See, Galin I, col. 1, lines 49-50. In further direct contrast, Galin indicates that "…the smaller pupil reduces vision, particularly in dim light." See, Galin, col. 1, lines 37-38. Further, from a list of at least six possible active agents, the preferred and only working example in Galin is directed to a solution that contains thymoxamine, and thus, the improved effect of a phentolamine-based solution on vision in dim light as claimed should not be deemed an inherent property of the Galin solution. Indeed, Galin is directed to the use of alpha adrenergic blocking agents to aid in the fixation of intraocular lenses (See, Galin, col. 1, lines 4-5) and not the effective reduction of pupil size to improve vision in dim light as claimed.

Again, the claimed ophthalmic formulation includes a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount and in a single dose per day of use to contract a pupil of a human patient's eye in dim light so that the

pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. As previously discussed, Applicant has demonstrated that a phentolamine-based formulation has enhanced effects on pupil reduction than other types of alpha 1 antagonist-based formulations, thus improving vision in dim light due to enhanced pupil reduction. Contrary to the Patent Office position, such unexpected results as embodied by the claimed invention are further supported by the Affidavit of Gerald Horn, M.D dated October 28, 2007 (Affidavit) as previously submitted in this case along with Applicant's Response dated April 15, 2008, another copy of the Affidavit is submitted herewith as Exhibit I for convenience. See Affidavit, for example, on pages 1 and 2, at paragraph 4:

> [t]he claimed phentolamine-based formulation inhibits pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Therefore, pupil size is optimized to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. Moreover, this result was unexpected since conventional ophthalmology indicated that reducing pupil size in dim light would cause vision acuity to deteriorate.

Contrary to the Patent Office position, Galin fails to recognize the claimed ophthalmic formulation with phentolamine in a therapeutically effective amount thereby effectively reducing pupil size to improve vision in dim light as claimed and as previously discussed. Again and in direct contrast, Galin indicates that "...the smaller pupil reduces vision, particularly in dim light". Moreover and in further direct contrast, Galin indicates that "[t]he approximately one drop dose can be repeated several times per day..." Therefore, Applicant does not believe Galin provides sufficient teaching to render unpatentable the phentolamine-based ophthalmic formulation that improves vision in dim light as presently claimed, and thus, the anticipation and obviousness rejections in view of Galin should be withdrawn. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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